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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,076	11/14/2005	Adam Rubin	10733.0002	2551

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,076	RUBIN ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of December 23, 2008 does not render the application allowable.

Status of the Rejections Pending since the Office action of December 23, 2008

2. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz et al. US 6,214,191 B1 ("Wiktorowicz") in view of Zanzucchi et al. US 5,755,942 ("Zannzucchi") and Simpson et al. US 6,143,152 ("Simpson"), and Cahill et al. EP 1044716 A1 ("Cahill").

Wiktorowicz discloses a micro fluid biomolecule separation system (abstract) comprising a primary separating path (160) and one or more secondary process paths

(170), said primary separating path being in the form of a separating coating carried on a substrate (col. 06:61-67 and col. 10:01-08), wherein said separating coating comprising one or more separating layers (col. 10:01-08), at least one separating layer consisting of or comprises one or more pH active components comprising pH active groups defined as chemical groups that are capable of being protonated or deprotonated in aqueous environments (col. 06:61-67 and col. 10:01-08), said fluid biomolecule separation system comprises means for applying a voltage over the primary separating path (col. 07:35-52), the or each secondary process path(s) comprising one or more inlets in liquid communication with the primary separating path, said one or more inlets being placed along or extends along the primary separating path (note inlets for microchannels 170 along upper edge 126a), whereby biomolecules separated along the primary path is capable of being introduced into the secondary process path(s) for being processed further (col. 07:47-54).

. Wiktorowicz does not mention (1) the thickness of the separating coating, and (2) having the system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre.

As for the claimed coating thickness range it should be first noted that the separating coating in Wiktorowicz may be an isoelectric focusing pKa gradient. See col. 06:61-67; col. 06:06-14; and col. 09:58 – col. 10:25. Cahill discloses isoelectric focusing pKa gradient coatings for use in electrophoresis microchannels. See the abstract. The coatings disclosed by Cahill may be used in microchannels having a height of only 10 nm. See paragraphs [0010] and [0020]. So Cahill implicitly discloses

separating coatings with a thickness between 0.01 and 15 µm. Thus, in light of Cahill to use isoelectric focusing coatings having a thickness between 0.01 and 15 µm is merely simple substitution of one known element for another to obtain predictable results. Moreover, an advantage of the separating coatings Cahill discloses is that they avoid material losses that occur in other types of pH gradients due to solid pH barriers formed in gels and membranes. See [0006].

As for having the system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre, Wiktorowicz has the system in the form of a disc device begin essentially rectangular comprising a centre, the microchannel structure being arranged around the centre. See Figures 3 and 4. Changing the shape of the disc form rectangular to circular is a mere matter of choice that has no effect on the operation of the device. MPEP 2144.04.IV.B. Moreover as shown by Simpson and Zanzucchi it was known at the time of the invention to have a microfluidic system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre. See Figure 1 in Simpson and Figure 1B in Zanzucchi. Thus, the substitution of a circular disc for a rectangular disc is also simple substitution of one known element for another to obtain predictable results.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. US 6,676,819 B1 ("Liu"), Zanzucchi et al. US 5,755,942 ("Zannzucchi"), Simpson et al. US 6,143,152 ("Simpson"), and Cahill et al. EP 1044716 A1 ("Cahill").

Liu discloses a micro fluid biomolecule separation system (abstract and col. 01:34-44) comprising a primary separating path (14) and one or more secondary process paths (60), said primary separating path being in the form of a separating coating carried on a substrate (col. 10:60 – col. 11:26), wherein said separating coating comprising one or more separating layers (col. 10:60 – col. 11:26), at least one separating layer consisting of or comprises one or more pH active components comprising pH active groups defined as chemical groups that are capable of being protonated or deprotonated in aqueous environments (col. 10:60 – col. 11:26 and col. 02:30-60), said fluid biomolecule separation system comprises means for applying a voltage over the primary separating path (col. 10:18-30 and col. 13:01-09), the or each secondary process path(s) comprising one or more inlets in liquid communication with the primary separating path, said one or more inlets being placed along or extends along the primary separating path (note inlets for microchannels 60 especially in Figures 5, 6, 8, 9A, 9B, and 10-12), whereby biomolecules separated along the primary path is capable of being introduced into the secondary process path(s) for being processed further (col. 13:15-30 and col. 14:05-15).

As for the claimed coating thickness range it should be first noted that the separating coating in Liu may be an isoelectric focusing pKa gradient. See

Col. 11:11-26. Cahill discloses isoelectric focusing pKa gradient coatings for use in electrophoresis microchannels. See the abstract. The coatings disclosed by Cahill may be used in microchannels having a height of only 10 nm. See paragraphs [0010] and [0020]. So Cahill implicitly discloses separating coatings with a thickness between 0.01 and 15 μm. Thus, in light of Cahill to use isoelectric focusing coatings having a thickness between 0.01 and 15 μm is merely simple substitution of one known element for another to obtain predictable results. Moreover, an advantage of the separating coatings Cahill discloses is that they avoid material losses that occur in other types of pH gradients due to solid pH barriers formed in gels and membranes. See [0006].

As for having the system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre, Liu has the system in the form of a disc device begin essentially rectangular comprising a centre, the microchannel structure being arranged around the centre. See Figures 3 and 4. Changing the shape of the disc form rectangular to circular is a mere matter of choice that has no effect on the operation of the device. MPEP 2144.04.IV.B. Moreover as shown by Simpson and Zanzucchi it was known at the time of the invention to have a microfluidic system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre. See Figure 1 in Simpson and Figure 1B in Zanzucchi. Thus, the substitution of a circular disc for a rectangular disc is also simple substitution of one known element for another to obtain predictable results.

8. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. US 6,974,526 B2 ("Lee"), Zanzucchi et al. US 5,755,942 ("Zannzucchi"), Simpson et al. US 6,143,152 ("Simpson"), and Cahill et al. EP 1044716 A1 ("Cahill").

Lee discloses a micro fluid biomolecule separation system (abstract) comprising a primary separating path (3) and one or more secondary process paths (4), said primary separating path being in the form of a separating coating carried on a substrate (col. 05:45-50 and claims 2 and 9), wherein said separating coating comprising one or more separating layers (col. 10:60 – col. 11:26), at least one separating layer consisting of or comprises one or more pH active components comprising pH active groups defined as chemical groups that are capable of being protonated or deprotonated in aqueous environments (col. 10:60 – col. 11:26), said fluid biomolecule separation system comprises means for applying a voltage over the primary separating path (col. 04:21-24), the or each secondary process path(s) comprising one or more inlets in liquid communication with the primary separating path, said one or more inlets being placed along or extends along the primary separating path (see Figures 2-9), whereby biomolecules separated along the primary path is capable of being introduced into the secondary process path(s) for being processed further (col. 02:01-19 and claim 7).

As for the claimed coating thickness range it should be first noted that the separating coating in Liu may be an isoelectric focusing pKa gradient. See col. 05:45-50 and claims 2 and 9. Cahill discloses isoelectric focusing pKa gradient coatings for use in electrophoresis microchannels. See the abstract. The coatings disclosed by

Cahill may be used in microchannels having a height of only 10 nm. See paragraphs [0010] and [0020]. So Cahill implicitly discloses separating coatings with a thickness between 0.01 and 15 μm. Thus, in light of Cahill to use isoelectric focusing coatings having a thickness between 0.01 and 15 μm is merely simple substitution of one known element for another to obtain predictable results. Moreover, an advantage of the separating coatings Cahill discloses is that they avoid material losses that occur in other types of pH gradients due to solid pH barriers formed in gels and membranes. See [0006].

As for having the system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre, Lee has the system in the form of a disc device begin essentially rectangular comprising a centre, the microchannel structure being arranged around the centre. See Figures 3 and 4. Changing the shape of the disc form rectangular to circular is a mere matter of choice that has no effect on the operation of the device. MPEP 2144.04.IV.B. Moreover as shown by Simpson and Zanzucchi it was known at the time of the invention to have a microfluidic system be in the form of a disc device begin essentially circular comprising a centre, the microchannel structure being arranged around the centre. See Figure 1 in Simpson and Figure 1B in Zanzucchi. Thus, the substitution of a circular disc for a rectangular disc is also simple substitution of one known element for another to obtain predictable results.

Requirement for Information

9. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

10. In response to this requirement, please provide a copy of each of the following items of art referred to in the specification, page 5, lines 04-22. Applicant has amended claim 1 to require a separating coating with a thickness of between 0.01 and 15 μm carried on the substrate. The cited specification passage refers to a Danish patent application for an exemplary coating. Applicant is required to provide a copy of the application if it was ever published, became a patent, or otherwise became publicly available.

11. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

12. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

13. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Final Rejection

14. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
April 7, 2009